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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known

Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
SH	A1	4,621,079		Lachnit-Fixson et al.	11-04-1986	
SH	A2	5,569,652	A1	Beier et al.	10-29-1996	

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		Office ³	Number ⁴	Kind Code ⁵ (if known)			
SH	B1	WO	97/11680	A2	Elliesen et al.	04-03-1997	
SH	B2	CA	2,188,907		Dittgen et al.	02-27-2001	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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SH	C1	Prosecution History of Corresponding international Application No. PCT/IB00/01213 at EPO.	
	C2	Casper et al., "Estrogen and Interrupted Progestin: A New Concept for Menopausal Hormone Replacement Therapy," <i>American Journal of Obstet Gynecol</i> , Vol. 168, No. 4, pp. 1188-1196.	
	C3	Lignieres, "Oral Micronized Progesterone," <i>Clinical Therapeutics</i> , Vol. 21, No. 1, 1999, pp. 41-60.*	
	C4	Nickisch et al., "Acid-Catalyzed Rearrangements of 15 β ,16 β -methylene-17 α -pregnene-21,17 α -carbolactone Derivatives," <i>Tetrahedron Letters</i> , Vol. 27, No. 45, 1986, pp. 5463-5466.	
	C5	Translation of Cite No. C4.	
	C6	Shah et al., "Preformulation Study of Etoposide: identification of Physicochemical Characteristics Responsible for the Low and Erratic Oral Bioavailability of Etoposide," <i>Pharmaceutical Research</i> , Vol. 6, May 1999, pp. 408-412.	
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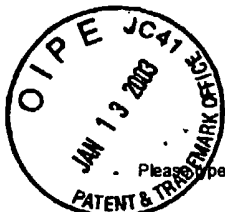
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Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

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SH	C9	Berlin et al., "Phase I and Pharmacokinetic Study of a Micronized Formulation of Carboxyamidotriazole, A Calcium Signal Transduction Inhibitor: Toxicity, Bioavailability And The Effect Of Food," <i>Clinical Cancer Research</i> , January 2002, Vol. 8, No. 1, pp. 86-94	
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	C11	Duclos et al., "About A Pharmacokinetic Study Of Progesterone In Cemeils," <i>Eur-J-Drug-Metab-Pharmacokin</i> , Vol. 15, No. 2, Suppl., Abstr. 226, 1990.	
	C12	Fell et al., "Bioavailability Of Griseofulvin From A Novel Capsule Formulation," <i>The Journal Of Pharmacy And Pharmacology</i> , 1978, Vol. 30, No. 8, pp. 479-82.	
	C13	Hartmann et al., "Comparison Of Galenic Formulations Of Orlistate (Tetrahydrolipstatin). A Pharmacological Approach," <i>Drug Investigation</i> , 1993, Vol/Iss/Pg. 5/1 (44-50).	
	C14	Kohn et al., "Pharmacokinetics And Bioavailability Of Diltiazem (CRD-401) In Dog," <i>Arzneimittel-Forschung</i> , 1977, Vol. 27, No. 7, pp. 1424-8.	
	C15	Hsiao et al., "Method For Preparing An Oral Formulation Containing Acid-Sensitive Drugs," <i>Standard Chem. & Pharm. Co., Ltd.</i>	
	C16	Klokkers et al., "Stabilization Of Acid Sensitive Benzimidazoles With Amino Acid/Cyclodextrin Combinations."	
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SH	C19	Bozdog et al., "Formulation And Stability Evaluation Of Enteric-Coated Omeprazole Formulations," <i>S.T.P. Pharma Sciences</i> , Vol. 9, No. 4, 1999, pp. 321-327.	

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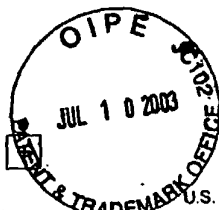
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		Application Number	09/654,227		
		Filing Date	August 31, 2000		
		First Named Inventor	Wolfgang HEIL et al.		
		Group Art Unit	1617		
		Examiner Name	M. Bahar		
Sheet	1	of	1	Attorney Docket Number	PLOVIN-1A

U.S. PATENT DOCUMENTS					
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		Number	Kind Code ² (if known)		
SH	A1	5,827,843		Koninckx	10-27-1998

FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Office ⁴	Number ⁴	Kind Code ⁵ (if known)				
SH	B1	WO	98/27929	A2	Nashed	07-02-1998		Yes

NON PATENT LITERATURE DOCUMENTS					
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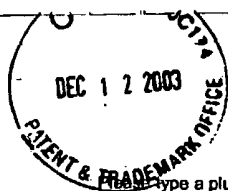
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U.S. PATENT DOCUMENTS

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		Number	Kind Code ² (if known)		
SH	A1	4,217,347		Horovitz et al.	08-12-1980
	A2	5,001,113		Williams et al.	03-19-1991
	A3	5,824,667		Spona et al.	10-20-1998
	A4	6,083,528		Elliesen et al.	07-04-2000
	A5	6,121,465		Mohr et al.	09-19-2000
	A6	RE37,564		Spona et al.	02-26-2002

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SH	B1	DE	3022337	A1	Eiger et al.	01-07-1982		
	B2	WO	95/07081	A1	Koninckx	03-16-1995		
	B3	WO	97/10827	A1	Petit et al.	03-27-1997		
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SH	C1	Elstein et al., "Advances in Oral Hormonal Contraception," <i>Zentralbl Gynakol</i> 117 (1995) 559-565	
	C2	Oelkers et al., "Effects of the new progestogen and antimineralocorticoid dihydrospirorenone," <i>Acta Endocrinologica</i> 1992: 126 Suppl. 4, p. 71	
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	C4	Oelkers, "Effects of oral contraceptives on the renin - aldosterone system: overview and report on a new natriuretic progestogen," <i>Advances in Contraception</i> , 7 Suppl. 3 (1991) 195-206	
SH	C5	Kincl et al., "Increasing Oral Bioavailability of Progesterone by Formulation," <i>Journal of Steroid Biochemistry</i> , 1978, Vol. 9, pp. 83-84	

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SM	C6	Whitehead et al., "Absorption and metabolism of oral progesterone," <i>British Medical Journal</i> , 22 March 1980, pp. 825-827	
	C7	Maxson et al., "Bioavailability of oral micronized progesterone," <i>Fertility and Sterility</i> , Vol. 44, No. 5, November 1985, pp. 622-626	
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	C9	Hargrove et al., "Absorption of oral progesterone is influenced by vehicle and particle size," <i>Am J Obstet Gynecol</i> , Vol. 161, No. 4, October 1989, pp. 948-951	
	C10	Kohno et al., "Pharmacokinetics and Bioavailability of Diltiazem (CRD-401) in Dog," <i>Arzneim.-forsch./Drug Res.</i> , 27 (II), No. 7 (1977), pp. 1424-1428	
	C11	Nürnberg, "Manufacturing and Properties of Pharmaceutical Spray-Dried Products," <i>Acta Pharmaceutica Hungarica</i> 48. 19-35. 1978 (and English translation)	
	C12	Lehto et al., "The Effect of pH on the In-vitro Dissolution of Three Second-generation Sulphonylurea Preparations: Mechanism of Antacid-sulphonylurea Interaction," <i>J. Pharm. Pharmacol.</i> 1996, 48: 899-901	
	C13	Clarke et al., "Factors Influencing Comparative Bioavailability of Spironolactone Tablets," <i>Journal of Pharmaceutical Sciences</i> , Vol. 66, No. 10, October 1977, pp. 1429-1432	
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	C15	Berger et al., (1992) "Influence of Different Progestogens on Blood Pressure of Non-Anaesthetized Male Spontaneously Hypertensive Rats" <i>Contraception</i> 46: 83-97	
	C16	Skouby, (2000) "The rationale for a wider range of progestogens" <i>Climacteric</i> , Vol. 3, (Suppl. 2): 14-20	
	C17	Norman et al., (2000) "Drospirenone" <i>Drugs of the Future</i> 2000, 25(12): 1247-1256	
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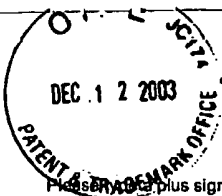
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NON PATENT LITERATURE DOCUMENTS

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64	C21	Krause et al., "Isolation and Identification of Spirorenone Metabolites from the Monkey (<i>Macaca Fascicularis</i>)," <i>Steroids</i> , Vol. 40, No. 1, July 1982, pp. 81-90	
	C22	Krause et al., "Determination of Plasma Levels of Spirorenone, a New Aldosterone Antagonist, and One of its Metabolites by High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> , 230 (1982) 37-45	
	C23	"Spirorenone," <i>Drugs of the Future</i> , Vol. 10, No. 6, 1985, pp. 479-481	
	C24	Wilson et al., (1984) "A prospective controlled study of the effect on blood pressure of contraceptive preparations containing different types and dosages of progestogen" <i>Brit. J. Obstet Gynecol</i> 91, 1254-1260	
	C25	Nichols et al., (1993) "Effect of four combined oral contraceptives on blood pressure in the pill-free interval" <i>Contraception</i> 47, 367-376 (1993)	
	C26	Oelkers et al., (1974) "Effects of Progesterone and Four Synthetic Progestagens on Sodium balance and the Renin-Aldosterone System in Man" <i>J. Clin. Endocrinol Metab</i> 39, 882-890	
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	C28	Luotola, "Blood Pressure and Hemodynamics in Postmenopausal Women During Estradiol-17 β Substitution," <i>Annals of Clinical Research</i> , Vol. 15, Suppl. 38 1983	
	C29	Mashchak, et al., "Estrogen Replacement Therapy and Hypertension," <i>The Journal of Reproductive Medicine</i> , Vol. 30, No. 10 (Supp)/October 1985, p. 805-810	
	C30	Rajkumar et al., "Hormonal Therapy Increases Arterial Compliance in Postmenopausal Women," <i>JACC</i> , Vol. 30, No. 2, August 1997:350-6	
	C31	Hayward et al., "Effect of hormone replacement therapy on non-invasive cardiovascular haemodynamics," <i>Journal of Hypertension</i> , 1997, Vol. 15, No. 9, p.987-993	
	C32	Mercuro et al., "Estradiol-17 β Reduces Blood Pressure and Restores the Normal Amplitude of the Circadian Blood Pressure Rhythm in Postmenopausal Hypertension," <i>American Journal of Hypertension</i> , Vol. 11, No. 8, Part 1, pp. 909-913	
	C33	Hayward et al., "Effect of Combination Hormone Replacement Therapy on Ambulatory Blood Pressure and Arterial Stiffness in Diabetic Postmenopausal Women," <i>American Journal of Hypertension</i> , July 2001, Vol. 14, No. 7, Part 1, pp. 699-703	
	C34	Wren et al., "The effect of type and dose of oestrogen on the blood pressure of post-menopausal women," <i>Maturitas</i> , 5 (1983) 135-142	
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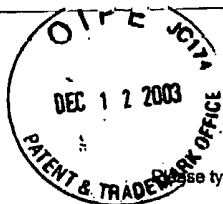
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	09/654,227		
		Filing Date	August 31, 2000		
		First Named Inventor	Wolfgang HEIL et al.		
		Group Art Unit	1617		
		Examiner Name	M. Bahar		
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SH	C36	Seely et al., "Estradiol With or Without Progesterone and Ambulatory Blood Pressure in Postmenopausal Women," <i>The American Heart Association, Inc.</i> , May 1999, 1190-1194
	C37	Mercuro et al., "Effects of Acute Administration of Transdermal Estrogen on Postmenopausal Women with Systemic Hypertension," <i>The American Journal of Cardiology</i> , Vol. 80, September 1, 1997, 652-655
	C38	"Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women," <i>JAMA</i> , January 18, 1995, Vol. 273, No. 3, 199-208
	C39	Pripp et al., "A randomized trial o effects of hormone replacement therapy on ambulatory blood pressure and lipoprotein levels in women with coronary artery disease," <i>Journal of Hypertension</i> , 1999, Vol. 17, No. 10, 1379-1386
	C40	Manhem et al., "Transdermal oestrogen reduces daytime blood pressure in hypertensive women," <i>Journal of Human Hypertension</i> , (1998) 12, 323-327
	C41	Ittersum et al., "Ambulatory-Not Office-Blood Pressures Decline During Hormone Replacement Therapy in Healthy Postmenopausal Women," <i>American Journal of Hypertension</i> , 1998, Vol. 11, No. 10, part 1, 1147-1152
	C42	Carara et al., "Abstracts Thirtieth Annual Meeting American College of Clinical Pharmacology September 23-25, 2001, Vienna, Virginia," <i>J Clin Pharmacol</i> , 2001; 41:1014-1033
	C43	Epstein, "Aldosterone and the hypertensive kidney: its emerging role as a mediator of progressive renal dysfunction: a paradigm shift," <i>Journal of Hypertension</i> , 2001, Vol. 19, No. 5, 829-834
	C44	Duprez et al., "Aldosterone and Vascular Damage," <i>Current Hypertension Reports</i> , 2000, 2:327-334
	C45	Pitt et al., "The Effect of Spironolactone on Morbidity and Mortality in Patients with Severe Heart Failure," <i>The New England Journal of Medicine</i> , Vol. 341, No. 10, September 2, 1999, 709-717
	C46	Farquharson et al., "Spironolactone Increases Nitric Oxide Bioactivity, Improves Endothelial Vasodilator Dysfunction, and Suppresses Vascular Angiotensin I/Angiotensin II Conversion in Patients with Chronic Heart Failure," <i>Circulation</i> , February 15, 2000, 594-597
	C47	MacFadyen et al., "Aldosterone blockade reduces vascular collagen turnover, improves heart rate variability and reduces early morning rise in heart rate in heart failure patients," <i>Cardiovascular Research</i> , 35 (1997) 30-34
SH	C48	Chrysostomou et al., "Spironolactone in Addition to ACE Inhibition to Reduce Proteinuria in Patients with Chronic Renal Disease," <i>N Engl J Med</i> , Vol. 345, No. 12, September 20, 2001, 925-926

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Application Number		09/654,227			
Filing Date		August 31, 2000			
First Named Inventor		Wolfgang HEIL et al.			
Group Art Unit		1617			
Examiner Name		M. Bahar			
Attorney Docket Number		PLOVIN-1A			
Sheet	1	of	1		

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SM	C1	An invitation (one page) for and 21 slides shown in an oral presentation held on February 17, 1988 in Berlin, Germany, entitled "Studies on pH-dependent Isomerization of Pregnene-17,21-Carbolactones," by Johannes W. Tack. (Original in German with English translation.)	
SM	C2	Sattar, et al., J.Clin.Endocrin.&Metab., Vol. 82, No. 8, 1483-2491 (1997).	
	C3		

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Respectfully submitted,

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Attorney Docket No.: PLOVIN-1ADate: February 26, 2004

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Sheet 1 of 1

Applicant's Name: 09/654 237

Filing Date: August 31, 2000

First Named Inventor: Wolfgang H. H. H. H. H.

Group A Unit: 1817

Applicant's Name: M. Bahr

Attorney Docket Number: PLOVIN-1A

U.S. PATENT DOCUMENTS

Examiner Index	Case No.	U.S. Patent Number	Kind Code (if known)	Name of Patentee or Applicant of U.S. Patent	Date of Publication of U.S. Patent (MM-DD-YYYY)
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C1		An invitation (one page) for and 11 slides shown in an oral presentation held on February 17, 1998 in Berlin, Germany, entitled "Rudges on pre-dependent identification of Pregnant-17,21-Carboxylates, by Johannes W. Tack, (Original in German with English translation.)	
C2		Bahr, et al., J. Clin. Endocrin., 1997, Vol. 82, No. 6, 1452-1451 (1997)	
C3			

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